K090214

510(K) SUMMARY
(As required by 21 CFR 807.92(a))

MAR 13 2009

Submitter Information	Company: Verathon Inc. 20001 North Creek Parkway Bothell, WA 98011 Phone: 425-867-1348 ext.5642 Fax: 425-883-2896 Email: krisn@verathon.com Contact: Kristian Nielsen Regulatory Affairs Specialist Date: January 29, 2009
Device Information	
Trade/Proprietary Name:	Verathon Inc. BladderScan® BVM 9500 Ultrasound System
Common Name:	Diagnostic Ultrasound System with Accessories
Classification Name(s):	Regulatory Class: II Review Category: Tier II Classification Panel: Radiology Ultrasonic Pulsed Echo Imaging System • FR Classification 892.1560 • Product Code 90-IYO Diagnostic Ultrasound Transducer • FR Classification 892.1570 • Product Code 90-ITX
Predicate Device(s):	Verathon BladderScan® BVI 9400 Ultrasound System (K071217) And Verathon BladderScan® BVM 6500 Ultrasound System (K030763)
Device Description:	The BladderScan® BVM 9500 is a B-mode ultrasonic

	instrument, portable and battery operated, intended for the noninvasive measurement of urinary bladder volume and bladder mass. The BladderScan® BVM 9500 calculates the bladder volume and mass using patented Vmode® technology. Vmode ultrasound is easy to use and comfortable for the patient. When you release the scan button, within seconds, the Vmode technology measures ultrasonic reflections on multiple planes inside the body and produces a 3-dimensional image. Based on this image, the BladderScan® calculates and displays the bladder volume and bladder mass. Volume measurements made with Vmode ultrasound are more accurate than those from conventional 2-dimensional ultrasound, as they are based on a more complex, 3-D image of the bladder. Bladder volume and mass, mode (uterus detection or standard BladderScan), directional aiming with real-time feedback, battery status, and usage rate indicators are all displayed on the BladderScan® BVM 9500 LCD display. The instrument contains a thermal printer that will allow the user to print exams with a single button click.
Intended Use:	(Same as previously cleared Verathon BVM 6500 Ultrasound System): The BladderScan® BVM 9500 is intended to project ultrasound energy through the lower abdomen to obtain an image of the bladder and measure urinary bladder volume and mass non-invasively.
Comparison of Required Technological Characteristics:	The Verathon Inc. BladderScan® BVM 9500 Ultrasound System retains the same bladder volume measurement features of the Verathon inc. BladderScan® BVI 9400 System (K071217), but also has the Bladder mass measurement function and intended use as the previously cleared Verathon Inc. BladderScan® BVM 6500 (K030763). The BVM 9500 is identical to the BVI 9400, with regards to hardware and calibration method however, the BVM 9500 transducer has been changed to a tri-frequency transducer for better bladder detection and measurement.

The Verathon Inc. BladderScan® BVM 9500's center section of the transducer is generating higher-frequency ultrasound at 7.3MHz. This special design is for bladder wall thickness measurement, which can yield higher resolution information and improves the thickness measurement accuracy. The ultrasonic power transmitted from the system is not user adjustable.

The portable Verathon Inc. BladderScan® BVM 9500 Ultrasound System is applied to the patient's abdomen along with Sontac Ultrasound Coupling Gel to obtain bladder volume and bladder mass. The BVM9500 Ultrasound System transducer collects two group of information: Group 1 includes cross-sectional Bmode images from 3MHz signal and the harmonic ratio from 1.74MHz; Group 2 includes the RF signal from higher frequency signal at 7.3MHz. Then the BVM9500 Ultrasound System utilizes the first group information to automatically calculate the urine volume via volumetric integration. At the same time, the 3D bladder surface area is also calculated based on the segmentations from every plane. Bladder wall thickness is measured automatically based on the7.3MHz RF signal in the following step. The higher resolution guarantees the accuracy of the thickness measurement of the thin bladder wall. Lastly, the 3D bladder surface area and the bladder wall thickness are computed.

In order to demonstrate the BladderScan® accuracy claimed in 0270-0425 -xx-55, a third party vendor was contracted to build tissue equivalent phantoms with known dimensions. The supplier of the tissue equivalent phantoms is CIRS and is known for supplying medical imaging phantoms to the medical marketplace.

The tissue equivalent phantom is essentially a balloon which gets filled with urine mimicking material and then the filled balloon is surrounded with tissue mimicking material. This balloon is a known volume and wall thickness and can be compared to the BladderScan® measurements from the BVM 9500.

	Bladder volume and mass accuracy have been demonstrated by comparing the bladder mass and bladder volume phantom measurements to the measurements of the Verathon Inc. BladderScan® BVM 9500. The same procedures are used to prove the measurement accuracy of the previously cleared Verathon Inc.BVM 6500 (K030763) during production. The calibration system for the Verathon Inc. BladderScan® BVM 9500 Ultrasound System is exactly the same as the Verathon Inc. BladderScan® BVI 9400 Ultrasound System (K071217).
Summary and Conclusion of Non Clinical and Clinical Testing	Design and testing of the Verathon Inc. BladderScan® BVM 9500 Ultrasound System indicates that the BVM 9500 is substantially equivalent to the Verathon Inc. BladderScan® BVI 9400 Ultrasound System (K071217) for bladder volume measurements and equivalent to the Verathon Inc. BVM 6500 Ultrasound System (K030763) for bladder mass measurements. All acoustic output measurements for the BladderScan® BVM 9500 Ultrasound System remains within Pre-amendment limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2009

Mr. Kristian Neilsen
Regulatory Affairs Specialist
Verathon, Inc.
Corporate Headquarters
20001 North Creek Parkway
BOTHELL WA 98011

Re: K090214
Trade/Device Name: Verathon Inc. BladderScan® BVM 9500 Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: January 29, 2009
Received: January 29, 2009

Dear Mr. Neilsen:

This letter corrects our substantially equivalent letter of March 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Verathon Inc. BladderScan® BVM 9500 Ultrasound System, as described in your premarket notification:

Transducer Model Number

3.0 / 1.74 Second/ 7.3 MHz Third Harmonic Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K090214

Device Name: BladderScan® BVM 9500 Ultrasound System

Indications For Use:

- Abdomen, B-Mode, per Indications for Use Ultrasound Form
- The BladderScan® BVM 9500 is intended to project ultrasound energy through the lower abdomen to obtain an image of the bladder and measure urinary bladder volume and mass non-invasively.

Contraindications:

- The BladderScan® BVM 9500 is contraindicated for fetal use and for use on pregnant patients.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090214

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
System: BladderScan® BVM 9500 Ultrasound System
3.0 / 1.74 Second/ 7.3MHz Third Harmonic Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (Abdominal Aorta Measurement)							
	Peripheral vessel							
	Other (Bladder)	P						

N= new indication; P= previously cleared by FDA (K071217 & K030763)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
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